## IN THE UNITED STATES DISTRICT COURT WESTERN DISTRICT OF OKLAHOMA

<b>DESTINY HIATT, Individually, and as</b>	)	
Surviving Child, of JAMES MAXEY,	)	
Deceased,	)	
	)	
Plaintiff,	)	
	)	Case No. 5:24-cv-00991-J
v.	)	
	)	
ZOLL MEDICAL CORPORATION,	)	
	)	
Defendants.	)	

#### **AMENDED COMPLAINT**

COMES NOW, the Plaintiff, Destiny Hiatt, individually and as surviving child, of James Maxey, deceased, and for her claims for relief against the Defendant, ZOLL medical Corporation (hereinafter "ZOLL") alleges and states as follows:

### **PARTIES**

- 1. The Plaintiff, Destiny Hiatt, is, and at all times relevant to this action was, a citizen and resident of Oklahoma and is the surviving child of James Maxey, deceased.
- 2. Defendant, ZOLL, a developer, manufacturer and distributor of wearable cardioverter defibrillator devices is a foreign corporation with its principal place of business in the State of Massachusetts and the requisite minimum contacts in and within Oklahoma County, State of Oklahoma.

#### **JURISDICTION AND VENUE**

3. Plaintiff restates and re-alleges each of the previous paragraphs of this Petition as if fully rewritten.

4. This Court has jurisdiction and venue over this lawsuit in that the Defendants do business and have the requisite minimum contacts in and within Oklahoma County.

#### **FACTS**

- 5. Plaintiff restates and re-alleges each of the previous paragraphs of this Petition as if fully rewritten.
- 6. On July 13, 2022, Decedent, James Maxey, suffering from ischemic cardiomyopathy, had been prescribed a wearable cardioverter defibrillator by Jinok Chung, D.O. (non-party).
- 7. The wearable cardioverter defibrillator chosen by Dr. Chung, was designed, manufactured, marketed and distributed by Defendant, ZOLL. The specific vest was the ZOLL LifeVest 4000.
- 8. Defendant, ZOLL, designed, manufactured, marketed, and placed into the stream of commerce the above LifeVest 4000.
- 9. On or about October 8, 2022, Mr. Maxey was wearing the Defendant, ZOLL's LifeVest when the vest malfunctioned and sent excessive electric currents to him and caused his death. The LifeVest delivered at minimum fourteen (14) shocks to Mr. Maxey.
- 10. The Zoll LiveVest is designed to deliver multiple shocks if the wearer's heartbeat does not return to normal and the arrhythmia continues after the initial shock. However, the Zoll LifeVest by its design will not deliver more than five (5) treatment shocks to the wearer. Each shock delivers approximately 150 joules of electrical energy.

- 11. The Zoll LifeVest is designed to provide the patient with certain warnings, including warnings on the monitor of the device if the device is malfunctioning in any way. A malfunction with the charging system has been shown to cause the Zoll LifeVest to not deliver shocks appropriately. In this event, the device is supposed to provide a warning to the patient to contact Zoll immediately. Mr. Maxey did not receive any warning on the monitor of his device prior to receiving almost triple the number of shocks the device is designed and manufactured to deliver.
- 12. Because of the excessive shocks being delivered to Mr. Maxey, Zoll was alerted of the malfunction. A Zoll representative attempted to call Mr. Maxey. When Mr. Maxey did not answer, the representative called Mr. Maxey's daughter, Plaintiff Hiatt, and informed her the device had already delivered fourteen (14) shocks to Mr. Maxey. Ms. Hiatt called her father and could hear the device beeping and talking to Mr. Maxey. She could also hear Mr. Maxey clicking the button to turn the device off. Ms. Hiatt could hear that after Mr. Maxey's repeated attempts to turn the device off, the device remained on, as it continued beeping and talking to Mr. Maxey.
- 13. On or about October 8, 2022, Mr. Maxey died as a direct and proximate result of the excessive electric current from the Defendant's LifeVest.

# FIRST CAUSE OF ACTION STRICT PRODUCTS LIABILITY

14. Plaintiff restates and re-alleges each of the previous paragraphs of this Petition as if fully rewritten.

- 15. Defendant, ZOLL designed, manufactured, assembled, marketed, distributed, conveyed, sold and/or placed into the stream of commerce the aforementioned LifeVest 4000 in their ordinary course of business. A properly manufactured Zoll LifeVest would not have shocked Mr. Maxey fourteen (14) times. The Zoll LifeVest was designed to only deliver a maximum of five (5) shocks. Thus, it delivered nearly triple the amount of shocks the LifeVest was designed and should have been manufactured to deliver had Zoll followed required manufacturing regulations.
- 16. The manufacturing defect was the direct result of Zoll's failure to comply with relevant federal regulations in the manufacturing of the LifeVest.
- 20ll failed to establish and maintain procedures for implementing corrective and preventive action with respect to the LifeVest devices, including the subject LifeVest. Specifically, Zoll failed to, among other things, establish and maintain procedures for (1) analyzing processes, work operations, quality records, and other information to identify existing and potential causes of nonconforming product, (2) investigating the cause of nonconformities, (3) identifying appropriate actions needed to correct and prevent recurrence of nonconforming product, (4) verifying and validating that the appropriate actions to prevent and remedy nonconformities were effective, and (5) documenting the processes and actions discussed above.
- 18. Further, 21 CFR 820.30(g) required, but Zoll failed to validate the design of the LifeVest devices by failing, among other things, (1) to ensure that the devices

conformed to defined user needs and intended uses, and (2) to test the devices under actual or simulated use conditions.

- 19. 21 CFR 820.20(c) required, but Zoll's management failed to review the procedures it was required to, but did not implement to ensure that Zoll's quality systems, which were severely lacking, satisfied the requirements of the current Good Manufacturing Practice (CGMP) requirements and of Zoll's quality policy and objectives.
- 20. 21 CFR 820.198 required, but Zoll failed to establish procedures for reviewing complaints relating to the LifeVest devices, including their failure to work, and consequently, failed to adequately evaluate and investigate problems with non-conforming devices.
- 21. The subject LifeVest was defective and unreasonably dangerous as a result of a manufacturing defect. Specifically, the subject LifeVest was defective and unreasonably dangerous in that it delivered nearly triple the number of shocks it is designed to deliver, and in that it failed to turn off when Mr. Maxey attempted to turn the device off. It was also defective in that it provided Mr. Maxey no warning on the device itself that any issue was occurring within the device for which he should contact Zoll to address the issue. The LifeVest is designed to deliver such warning, and when properly manufactured would deliver such warning.
- 22. The manufacturing defect was the direct result of Zoll's failure to comply with applicable federal regulations noted above for manufacturing LifeVest devices, including the subject LifeVest, and for detecting and fixing manufacturing defects with LifeVest devices before placing them into the stream of commerce and with patients.

- 23. Further, Zoll's marketing and representations that the LifeVest would deliver the appropriate number of shocks to each wearer, and in no event would deliver more than five (5) shocks was false when made. Mr. Maxey relied on these statements in deciding to use the LifeVest. Zoll knew its marketing in this regard was false at the time it was made.
- 24. Said vest which Plaintiff's Decedent was wearing at the time of death failed and such failure directly caused and/or contributed to James Maxey sustaining severe and permanent injuries, pain and suffering, resulting in his death. Said vest was defective in design, and/or manufacture, and/or as a result of Defendants 'failure to provide appropriate warnings regarding the potential dangers associated with the use of said vest, including warnings regarding the risk of a failure such as was experienced by Plaintiff's Decedent. Said defects existed when James Maxey wore the vest on October 8, 2022 making the vest unreasonably dangerous beyond the contemplation of the ordinary user. Defendants are therefore strictly liable under the doctrine of manufacturers' products liability.
- 25. As a direct and proximate result of the defects existing in the vest designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendant, Plaintiff's Decedent suffered severe injuries to mind and body. As a direct result, Decedent, James Maxey suffered severe personal injuries to mind and body resulting in his death and has been damaged in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).
- 26. As a further result of the negligence of Defendant, Plaintiff, Destiny Hiatt, has incurred funeral and burial expenses; has suffered grief as a result of the loss of life of

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her father; and has suffered the loss of the love companionship of her father in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

### **SECOND CAUSE OF ACTION BREACH OF WARRANTIES**

- 27. Plaintiff restates and re-alleges each of the previous paragraphs of this Petition as if fully rewritten.
- 28. Defendant breached applicable implied and express warranties, including warranties of merchantability and fitness for a particular purpose. Further, Defendant failed to provide appropriate warnings regarding the potential dangers associated with the use of said vest, including warnings regarding the risk of a failure such as was experienced by Plaintiff's Decedent. Defendant's breach was the direct result of Zoll's failure to comply with applicable federal regulations noted above.
- 29. As a direct and proximate result of the breach of warranties of merchantability and fitness for a particular purpose existing with the vest designed, manufactured, marketed, distributed, sold and/or placed into the stream of commerce by the Defendant, Plaintiff's Decedent suffered severe injuries to mind and body. As a direct result, Decedent, James Maxey suffered severe personal injuries to mind and body resulting in his death and has been damaged in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).
- 30. As a further result of the negligence of Defendant, Plaintiff, Destiny Hiatt, has incurred funeral and burial expenses; has suffered grief as a result of the loss of life of

her father; and has suffered the loss of the love companionship of her father in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

### THIRD CAUSE OF ACTION PUNITIVE DAMAGES

- 31. Plaintiff restates and re-alleges each of the previous paragraphs of this Petition as if fully rewritten.
- 32. Defendant's conduct was reckless, willful, wanton and likely to lead to physical injury or death. In committing the tortious acts and omissions described herein, Defendant acted with actual malice and/or gross negligence which evidences a willful, wanton or reckless disregard for the safety of others.
- 33. As a direct and proximate result of the willful, wanton, intentional acts, and/or the willful, wanton, intentional and reckless failures to act by Defendant, Plaintiff suffered the aforementioned damages and, as such, Plaintiff demands that punitive damages be awarded against Defendant.

WHEREFORE, above premise considered, the Plaintiff, Destiny Hiatt, individually and as surviving child, of James Maxey, deceased, prays for both actual and punitive damages in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00), attorneys fees, interest, and costs associated with prosecuting the above claims, and for such other relief as this Court deems just and reasonable.

Respectfully submitted,

s/Derek K. Burch

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#### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the 3<sup>rd</sup> day of March 2025, that I electronically filed the foregoing with the Clerk of the Court by using CM/ECF. Notice of this filing will be sent by e-mail to all parties by operations of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic filing. Parties may access this filing through the Court's CM/ECF system.

s/Derek K. Burch
DEREK K. BURCH

ATTORNEY LIEN CLAIMED
JURY TRIAL DEMANDED